

PREMIER DIRECT_{INC.}

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July 27, 1999

Office of Special Nutritionals (HFS-450)
Center for Food Safety and Applied Nutrition
Food and Drug Administration
200 C Street, SW
Washington, D.C. 20204



RE: 21 U.S.C. Section 343(r)(6) Notification of Statements on Dietary Supplements

Dear Sir/Madam:

I hereby notify the Food and Drug Administration ("FDA") of the use of statements of nutritional support in the labeling of the Healthy Heart Kit dietary supplement. Premier Direct, Inc. is a manufacturer of Healthy Heart Kit.

Statements Being Made in the Labeling of Healthy Heart Kit

- (1) Support healthy arteries for better overall health
- (2) It is a wonderful way to support healthy arteries and the entire cardiovascular system
- (3) Support your arteries naturally
- (4) Chelo2Garde with EDTA: This special blend of vitamins and minerals developed at the Princeton Brain Bio Center supports cleansing of the blood vessels.
- (5) Ginkgo Biloba has the remarkable property of carrying oxygen. Also supports a healthy blood flow.
- (6) Contains B6, B12 and Folic Acid, which support homocysteine function and blood cells for heart health
- (7) Cold-pressed fish oils (pure marine lipid) support blood vessel walls.
- (8) Oxy-Life: adds valuable oxygen to the bloodstream
- (9) Support healthy blood vessels ... arterial oxygen ... circulation of antioxidants ... red blood cell function ... and blood pressure function

To the best of my knowledge, and based upon information and belief present at the time of executing this notice, I certify that this information is accurate and complete and Premier Direct, Inc. possesses substantiation that the statements are truthful and not misleading.

VP

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